DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

Ron Cohen, M.D.
President & Chief Executive Officer
Acorda Therapeutics, Inc.
420 Saw Mill River Road
Ardsley, NY 10502

RE: NDA 022250
AMPYRA® (dalfampridine) Extended Release Tablets
MA #223

WARNING LETTER

Dear Dr. Cohen:

This letter notifies Acorda Therapeutics, Inc. (Acorda) that the Office of Prescription Drug Promotion (OPDP) of the U.S. Food and Drug Administration (FDA) has become aware of a Consumer Print Ad (print ad) including information about AMPYRA® (dalfampridine) Extended Release Tablets (Ampyra) and inviting interested parties to attend a presentation regarding multiple sclerosis (MS), published in the February 10, 2013, issue of the Des Moines Sunday Register. This print ad is false or misleading because it omits risk information associated with the use of Ampyra. Thus, the print ad misbrands the drug in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 352(n) & 321(n), and FDA implementing regulation 21 CFR 202.1(e)(5). Acorda also did not comply with 21 CFR 314.81(b)(3)(i). These violations are concerning from a public health perspective because they suggest that Ampyra is safer than has been demonstrated.

Background

Below is the indication and summary of the most serious and most common risks associated with the use of Ampyra.[1]

According to its FDA-approved product labeling (PI), Ampyra is indicated to improve walking in patients with multiple sclerosis (MS). This was demonstrated by an increase in walking speed.

Ampyra is contraindicated in patients with a history of seizure, in patients with moderate or severe renal impairment, and in patients with a history of hypersensitivity to Ampyra or 4-

[1] This information is for background purposes only and does not necessarily represent the risk information that should be included in the promotional piece cited in this letter.

aminopyridine. The PI also includes Warnings and Precautions regarding risk of seizures, use in patients with renal impairment, concurrent treatment with other forms of 4-aminopyridine, anaphylaxis, and risk of urinary tract infections.

Furthermore, the PI indicates that the most frequently reported adverse events in patients taking Ampyra were urinary tract infection, insomnia, dizziness, headache, nausea, asthenia, back pain, balance disorder, multiple sclerosis relapse, paresthesia, nasopharyngitis, constipation, dyspepsia, and pharyngolaryngeal pain.

Prior Communication

False or misleading promotional materials by Acorda are particularly troubling considering OPDP expressed concerns regarding violative promotional activities as recently as June 21, 2012. On June 21, 2012, OPDP sent Acorda an Untitled Letter regarding an Ampyra Video Segment. The video cited in the Untitled Letter was false or misleading because it overstated the efficacy of the drug product and minimized important risk information associated with Ampyra. OPDP is concerned that Acorda is continuing to promote its prescription drug products in a violative manner.

Omission of Risk Information

Promotional materials are misleading if they fail to reveal facts that are material in light of representations made by the materials or with respect to consequences that may result from the use of the drug as recommended or suggested by the materials. The print ad is misleading because it presents efficacy claims for Ampyra, but fails to communicate any risk information. For example, the print ad includes the following claims and representations (emphasis in original):

- The company logo and name of the drug, with the language "**Has Multiple Sclerosis affected you or someone you care for?**"
- "AMPYRA® (dalfampridine) Extended Release Tablets, 10 mg is indicated as a treatment to improve walking in patients with Multiple Sclerosis (MS). This was demonstrated by an increase in walking speed."

The print ad, however, entirely omits any risk information, including contraindications, warnings and precautions, and the most frequently reported adverse events for Ampyra. By omitting the risks associated with the drug, the print ad misleadingly suggests that Ampyra is safer than has been demonstrated. We note that the print ad includes the statement, "This presentation is not medical advice or an attempt to provide medical advice. Talk to your healthcare provider to determine if AMPYRA is right for you." However, this does not mitigate the misleading omission of risk information from the print ad.

Failure to Submit Under Form FDA 2253

FDA regulations require companies to submit any labeling or advertising devised for promotion of the drug product at the time of initial dissemination of the labeling and at the time of initial publication of the advertisement for a prescription drug product. 21 CFR 314.81(b)(3)(i). Each submission is required to be accompanied by a completed transmittal Form FDA 2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) and is required to include a copy of the product's current product labeling. Acorda failed to submit a copy of the print ad referred to in this letter to FDA under cover of Form FDA 2253 at the time of its initial dissemination.

Conclusion and Requested Action

For the reasons discussed above, the print ad misbrands Ampyra in violation of the FD&C Act, 21 U.S.C. 352(n) & 321(n) and FDA implementing regulation 21 CFR 202.1(e)(5). Furthermore, Acorda did not comply with 21 CFR 314.81(b)(3)(i).

OPDP requests that Acorda immediately cease the dissemination of violative promotional materials for Ampyra such as those described above. Please submit a written response to this letter on or before August 8, 2013, stating whether you intend to comply with this request, listing all promotional materials (with the 2253 submission date) for Ampyra that contain violations such as those described above, and explaining your plan for discontinuing use of such violative materials. Because the violations described above are serious and repeated, we request, further, that your submission include a comprehensive plan of action to disseminate truthful, non-misleading, and complete corrective messages about the issues discussed in this letter to the audience that received the violative promotional material. In order to clearly identify the violative promotional piece and focus on the corrective message, OPDP recommends that the corrective piece include a description of the violative promotional piece, include a summary of the violative message, provide information to correct the violative message, and be free of promotional claims and presentations. To the extent possible, corrective messaging should be distributed using the same media, and generally for the same duration of time and with the same frequency that the violative promotional material was disseminated.

Please direct your response to the undersigned at the **Food and Drug Administration, Center for Drug Evaluation and Research, Office of Prescription Drug Promotion, 5901-B Ammendale Road, Beltsville, Maryland 20705-1266** or by facsimile at (301) 847-8444. To ensure timely delivery of your submissions, please use the full address above and include a prominent directional notation (e.g. a sticker) to indicate that the submission is intended for OPDP. Please refer to MA #223 in addition to the NDA number in all future correspondence relating to this particular matter. OPDP reminds you that only written communications are considered official.

The violations discussed in this letter do not necessarily constitute an exhaustive list. It is your responsibility to ensure that your promotional materials for Ampyra comply with each applicable requirement of the FD&C Act and FDA implementing regulations.

Failure to correct the violations discussed above may result in FDA regulatory action, including seizure or injunction, without further notice.

Sincerely,

{See appended electronic signature page}

Michael Sauers, MPP
Acting Division Director
Office of Prescription Drug Promotion

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

MICHAEL A SAUERS
07/25/2013